

WE CLAIM:

1. A vascular graft prosthesis comprising:
a polymeric tubular structure having a wall; and
interconnecting, uniformly shaped pores in the tube wall;
wherein at least 75% of the pores have diameters within 20 μm of one another.
2. The vascular graft prosthesis of Claim 1 wherein the tubular structure has an internal diameter in a range of 1-20 mm.
3. The vascular graft prosthesis of Claim 1 wherein the tubular structure has an internal diameter in a range of 2-6 mm.
4. The vascular graft prosthesis of Claim 1 wherein the average diameters of the pores are in a range of 10-300 μm .
5. The vascular graft prosthesis of Claim 1 wherein the average diameters of the pores are in a range of 40-110 μm .
6. The vascular graft prosthesis of Claim 1 wherein the polymeric tubular structure comprises an elastomer.
7. The vascular graft prosthesis of Claim 1 wherein the elastomeric polymeric tubular structure comprises a polyurethane.

8. The vascular graft prosthesis of Claim 1 wherein the elastomeric polymeric tubular structure comprises a segmented aliphatic polyurethane.

9. The vascular graft prosthesis of Claim 1 wherein the elastomeric polymeric tubular structure comprises a material selected from the group consisting of Pellethane, Chronoflex, Hydrothane, Estane, Elast-Eon, Texin, Biomer, Surethane, Corethane, Carbothane, Techoflex, Tecothane and Biospan.

10. The vascular graft prosthesis of Claim 1 wherein the pores are spherically shaped.

11. The vascular graft prosthesis of Claim 1 further comprising reinforcing fibers in the elastomeric polymeric tubular structure.

12. The vascular graft prosthesis of Claim 11 wherein the reinforcing fibers comprise a non-elastic, non-degradable material.

13. The vascular graft prosthesis of Claim 11 wherein the reinforcing fibers comprise an elastic, non-degradable material.

14. The reinforcing fibers of Claim 12 further comprising an elastic, non-degradable material.

15. The reinforcing fibers of Claim 12 further comprising a material degradable in vivo.

16. The reinforcing fibers of Claim 13 further comprising a material degradable in vivo.

17. The reinforcing fibers of Claim 14 further comprising a material degradable in vivo.

18. The vascular graft prosthesis of Claim 11 wherein the reinforcing fibers have diameters in a range of 10 to 100 micrometers.

19. The vascular graft prosthesis of Claim 1 wherein at least 85% of the pores have diameters within 20 μm of one another.

20. The vascular graft prosthesis of Claim 1 wherein at least 95% of the pores have diameters within 20 μm of one another.

21. The vascular graft prosthesis of Claim 1 wherein substantially all of the pores have diameters within 20 μm of one another.

22. The vascular graft prosthesis of Claim 1 wherein the pores have multiple sides.

23. A vascular graft prosthesis comprising:
an elastomeric polymeric tubular structure having a wall; and
interconnecting, uniformly shaped pores in the tube wall;
wherein at least 75% of the pores have volumes within $4.2 \times 10^{-6} \text{ mm}^3$
of one another.

24. The vascular graft prosthesis of Claim 23 wherein at least 85% of the pores have volumes within $4.2 \times 10^{-6} \text{ mm}^3$ of one another.

25. The vascular graft prosthesis of Claim 23 wherein at least 95% of the pores have volumes within $4.2 \times 10^{-6} \text{ mm}^3$ of one another.

26. The vascular graft prosthesis of Claim 23 wherein substantially all of the pores have volumes within $4.2 \times 10^{-6} \text{ mm}^3$ of one another.

27. A prosthetic heart valve comprising:
an elastomeric polymeric tubular structure having a wall; and
interconnecting, uniformly shaped pores in the tube wall;
wherein at least 75% of the pores have diameters within $20 \text{ }\mu\text{m}$ of one another.

28. A sewing ring comprising:
an elastomeric polymeric tubular structure having a wall; and
interconnecting, uniformly shaped pores in the tube wall;
wherein at least 75% of the pores have diameters within $20 \text{ }\mu\text{m}$ of one another.

29. A stent comprising:
an elastomeric polymeric tubular structure having a wall; and
interconnecting, uniformly shaped pores in the tube wall;
wherein at least 75% of the pores have diameters within $20 \text{ }\mu\text{m}$ of one another.

30. A method of making a prosthesis comprising the steps of:
providing at least one cylindrical mold in a casting device, with a central rod centrally positioned within the mold;
filling an annulus of the at least one mold with extractable filler particles;
injecting a graft material solution into the annulus, such that the graft material solution permeates spaces between the filler particles in the at least one mold;
precipitating graft material from the graft material solution;
removing the central rod from the at least one mold;
removing the graft material from the at least one mold; and
extracting the filler particles from the graft material.

31. The method of Claim 30, further comprising the steps of clamping the at least one mold between a top manifold and a bottom manifold of the casting device, and applying air pressure to the top manifold after the graft material solution is injected into the reservoir.

32. The method of Claim 30, further comprising the steps of clamping the at least one mold between a top manifold and a bottom manifold of the casting device, and applying a vacuum to the bottom manifold after the graft material solution is injected into the reservoir.

33. The method of Claim 31, further comprising the step of simultaneously applying a vacuum to the bottom manifold.

34. The method of Claim 30 wherein between 1 and 20 molds are inserted in the casting device.

35. The method of Claim 30 wherein the at least one mold comprises glass.

36. The method of Claim 30 wherein the at least one mold has an inside diameter about equal to a desired outside diameter of the vascular graft prosthesis.

37. The method of Claim 36 wherein the inside diameter of the at least one mold is in a range of 1.3-23 mm.

38. The method of Claim 36 wherein the inside diameter of the at least one mold is in a range of 2.3-8 mm.

39. The method of Claim 30 wherein the rod has an outside diameter about equal to a desired inner diameter of the vascular graft prosthesis.

40. The method of Claim 39 wherein the outside diameter of the rod is in a range of 1-20 mm.

41. The method of Claim 39 wherein the outside diameter of the rod is in a range of 2-6 mm.

42. The method of Claim 30 wherein the filler particles have diameters in a range of 10-300 μm .

43. The method of Claim 30 wherein the filler particles have diameters in a range of 40-110 μm .

44. The method of Claim 30, wherein the filler particles comprise spherical beads.

45. The method of Claim 30 wherein the filler particles comprise a polymer.

46. The method of Claim 30 wherein the graft material comprises a thermoplastic elastomer.

47. The method of Claim 30 wherein the graft material comprises a polyurethane.

48. The method of Claim 30 wherein the graft material comprises a segmented aliphatic polyurethane.

49. The method of Claim 30 wherein the graft material comprises a material selected from the group consisting of Pellethane, Chronoflex, Hydrothane, Estane, Elast-Eon, Texin, Biomer, Surethane, Corethane, Carbothane, Techoflex, Tecothane and Biospan.

50. The method of Claim 30 wherein the graft material solution comprises reinforcing fibers.

51. A biosynthetic heart valve made according to the method of Claim 30.

52. A sewing ring made according to the method of Claim 30.

53. A stent made according to the method of Claim 30.

54. A vascular graft prosthesis made according to the method of Claim 30.

55. A method of making a prosthesis comprising the steps of:
preparing a paste comprising an extractable filler and a graft material solution;

rolling a desired thickness of the paste onto a mandrel, wherein the mandrel has an outside diameter about equal to a desired inside diameter of the vascular graft prosthesis;

precipitating graft material from the graft material solution; and
extracting the filler from the graft material.

56. The method of Claim 55 wherein the graft material is precipitated from the graft material solution and the filler is extracted from the graft material simultaneously.

57. The method of Claim 55 wherein the outside diameter of the mandrel is in a range of 1-20 mm.

58. The method of Claim 55 wherein the outside diameter of the mandrel is in a range of 2-6 mm.

59. The method of Claim 55 wherein the thickness of the paste is in a range of 0.1-5 mm.

60. The method of Claim 55 wherein the thickness of the paste is in a range of 0.4-1.5 mm.

61. The method of Claim 55 wherein the filler comprises particles having diameters in a range of 10-300 μm .

62. The method of Claim 55 wherein the filler comprises particles having diameters in a range of 40-110 μm .

63. The method of Claim 55 wherein the filler comprises polymeric beads.

64. The method of Claim 55 wherein the graft material comprises a thermoplastic elastomer.

65. The method of Claim 55 wherein the graft material comprises a polyurethane.

66. The method of Claim 55 wherein the paste further comprises reinforcing fibers.

67. A biosynthetic heart valve made according to the method of Claim 55.

68. A sewing ring made according to the method of Claim 55.

69. A stent made according to the method of Claim 55.

70. A vascular graft prosthesis made according to the method of Claim 55.

71. A method of making a prosthesis comprising the steps of:
preparing a paste comprising an extractable filler and a graft material solution;

extruding the paste through an annular orifice;
precipitating graft material from the graft material solution; and
extracting the filler from the graft material.

72. The method of Claim 71 wherein the graft material is precipitated from the graft material solution and the beads are extracted from the graft material simultaneously.

73. The method of Claim 71 wherein the annular orifice has an outer diameter about equal to a desired outer diameter of the vascular graft prosthesis, and the outer diameter of the annular orifice is in a range of 1.1-25 mm.

74. The method of Claim 71 wherein the annular orifice has an outer diameter about equal to a desired outer diameter of the vascular graft prosthesis, and the outer diameter of the annular orifice is in a range of 2.1-11 mm.

75. The method of Claim 71 wherein the annular orifice has an inner diameter about equal to a desired inner diameter of the vascular graft prosthesis, and the inner diameter of the annular orifice is in a range of 1-20 mm.

76. The method of Claim 71 wherein the annular orifice has an inner diameter about equal to a desired inner diameter of the vascular graft prosthesis, and the inner diameter of the annular orifice is in a range of 2-6 mm.

77. The method of Claim 71 wherein the filler comprises particles having diameters in a range of 10-300 μm .

78. The method of Claim 71 wherein the filler comprises particles having diameters in a range of 40-110 μm .

79. The method of Claim 71 wherein the filler comprises polymeric beads.

80. The method of Claim 71 wherein the graft material comprises a thermoplastic elastomer.

81. The method of Claim 71 wherein the graft material comprises a polyurethane.

82. The method of Claim 71 wherein the paste further comprises reinforcing fibers.

83. A biosynthetic heart valve made according to the method of Claim 71.

84. A sewing ring made according to the method of Claim 71.

85. A stent made according to the method of Claim 71.

86. A vascular graft prosthesis made according to the method of Claim 71.

87. A method of making a prosthesis comprising the steps of:
Preparing a paste comprising an extractable filler and a graft material solution;

Depositing the paste in consecutive layers onto a mandrel, wherein the mandrel has an outside diameter about equal to a desired inside diameter of the vascular graft prosthesis;

Precipitating graft material from the graft material solution; and
Extracting the filler from the graft material.

88. The method of Claim 87 wherein the graft material is precipitated from the graft material solution and the filler is extracted from the graft material simultaneously.

89. The method of Claim 87 wherein the outside diameter of the mandrel is in a range of 1-20 mm.

90. The method of Claim 87 wherein the outside diameter of the mandrel is in a range of 2-6 mm.

91. The method of Claim 87 wherein the consecutive layers of the paste have a combined thickness in a range of 0.1-5 mm.

92. The method of Claim 87 wherein the consecutive layers of the paste have a combined thickness in a range of 0.4-1.5 mm.

93. The method of Claim 87 wherein the filler comprises particles having a diameter in a range of 10-300 μm .

94. The method of Claim 87 wherein the filler comprises particles having a diameter in a range of 40-110 μm .

95. The method of Claim 87 wherein the filler comprises polymeric beads.

96. The method of Claim 87 wherein the graft material is a thermoplastic elastomer.

97. The method of Claim 87 wherein the graft material is a polyurethane.

98. The method of Claim 87 wherein the paste further comprises reinforcing fibers.

99. A biosynthetic heart valve made according to the method of Claim 87.

100. A sewing ring made according to the method of Claim 87.

101. A stent made according to the method of Claim 87.

102. A vascular graft prosthesis made according to the method of Claim 87.

103. A method of making a prosthesis comprising the steps of:
extruding a thermoplastic elastomer with the aid of a blowing agent, to produce a foamed graft; and
annealing and reticulating the foamed graft to effect an open-cell structure.

104. The method of Claim 103 wherein the blowing agent comprises a physical blowing agent.

105. The method of Claim 103 wherein the blowing agent comprises a chemical blowing agent.

106. The method of Claim 103 wherein the blowing agent comprises physical and chemical blowing agents.

107. The method of Claim 103 wherein the thermoplastic elastomer comprises a polyurethane.

108. The method of Claim 103 wherein the thermoplastic elastomer further comprises reinforcing fibers.

109. A biosynthetic heart valve made according to the method of Claim 103.

110. A sewing ring made according to the method of Claim 103.

111. A stent made according to the method of Claim 103.

112. A vascular graft prosthesis made according to the method of Claim 103.